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Guidance for the Reregistration of Pesticide Products Containing Methidathion as the Active Ingredient

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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS
CONTAINING
METHIDATHION

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

REGISTRATION DIVISION

WASHINGTON, D.C.
JANUARY 13, 1983

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PRODUCTS AFFECTED BY THIS REREGISTRATION PROCESS

Following is a list of your products affected by this reregistration process. If this list is incomplete or inaccurate in any way, please notify the Product Manager (PM) identified in the letter.

Technical Methidathion
EPA Reg. No. 100-530

Methidathion 60S
EPA Reg. No. 100-531

Methidathion 50S
EPA Reg. No. 100-561

REGISTRANTS WITH PESTICIDE PRODUCTS CONTAINING
THE ACTIVE INGREDIENT

he information attached will allow registrants with pesticide products ontaining the above ingredient to contact one another regarding joint dat evelopment or sharing the cost of data development under section 3(c)(2)(f FIFRA. This information includes the following: EPA Registration No., ompany name, company's address, active ingredient, percentage of active ngredient and type of formulation such as Manufacturing Use Product (MUP), echnical Product (TP), wettable powder (WP), and emulsifiable concentrate EC).

METHIDATHION

Ciba-Geigy Corporation
Agricultural Division
P.O. Box 11422
Greensboro, NC 27409

EPA Reg. No. 100-530

Technical Methidathion (TP)--95% active ingredient

EPA Reg. No. 100-531

Methidathion 60S (MUP)--60% active ingredient

EPA Reg. No. 100-561

Methidathion 50S (MUP)--50% active ingredient

I. INTRODUCTION

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Each registrant of a currently registered product who wishes to continue to sell or distribute such product in commerce, must apply for reregistration.

A new review procedure has been developed. Under it, EPA publishes Guidance Documents, each of which discusses a particular pesticide active ingredient. Each Guidance Document summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have; compliance with standards of toxicity, composition, labeling, and packages; and satisfaction of the compensation provisions of FIFRA Section 3(c)(1)(D).

EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product, if the registrant fails to comply with the procedures for reregistration set forth in this Guidance Document.

This Guidance Document has been prepared to provide you, the registrant, with specific information on how you may maintain in effect your current registration(s). (Refer to the cover letter's attachment for a listing of your affected products.) If for any reason you decide to request that the Agency discontinue the registration of any of your products subject to the registration requirements in this document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the time frames outlined.

REGISTRATION STANDARD FOR METHIDATHION

II. Regulatory Position and Rationale

A. Introduction

This chapter presents the regulatory position of the Environmental Protection Agency, hereafter referred to as "the Agency", on all registered manufacturing-use products containing methidathion as the sole active ingredient. There are no current registrations that include methidathion in mixtures. The regulatory position contained in this guidance document reflects a review only of the manufacturing-use products of this chemical and not end-use products. Data necessitated by use patterns of "Special Local Need" registrations, authorized under Section 24(c) of the FIFRA, are considered in addition to registrations granted or pending under Section 3 of FIFRA. Future requests for registrations of substantially similar compounds will be covered by this guidance document. Dissimilar products will require amendments to this document.

The regulatory position is based on an evaluation of these products. Included in this document is the rationale for the Agency's position and the criteria for registration that result from the evaluation. A description of the chemical, labeling considerations and tolerance reassessment is also included. Data requirements are presented in tables A and B.

B. Background

Methidathion is the acceptable common name, recognized by the American National Standards Institute (1973), for 0,0-dimethyl phosphorodithioate S-ester with 4(mercaptomethyl)-2-methoxy-delta 2-1,3,4-thiadiazolin-5-one. It was developed under Ciba-Geigy Experiment Number GS-13005 and may alternately be identified by the registered trade names Supracide®, Ultracide® and Somonil®. The Chemical Abstracts Service (CAS) Registry number is 950-37-8. The Office of Pesticide Programs Internal Control Number (EPA Shaughnessy number) is 100301.

The technical material is manufactured in Switzerland for Ciba-Geigy Corporation. Their Agricultural Division in Greensboro, North Carolina is the sole formulator of methidathion in the United States.

Methidathion is formulated into three manufacturing-use products. There is a 95 percent technical product, and two formulation intermediate products of 50 and 60 percent. There is also a 24.4 percent active ingredient end-use emulsifiable concentrate, which is a restricted use product.

Methidathion is a federally registered insecticide/acaricide used predominantly on citrus and alfalfa, as well as other agricultural crops, to control a broad spectrum of insect and mite pests. The emulsifiable concentrate formulation is diluted with water and can be applied both aerially and with ground equipment, including airblast and hydraulic sprayers.

C. Regulatory Position

Based on a review and evaluation of all available data and other relevant information, the Agency has made the following determinations:

1. Both currently registered and new manufacturing-use pesticide products containing methidathion as the sole active ingredient, may be reregistered or registered for sale, distribution and use, subject to the terms and conditions specified within this guidance document. Applicants having products not conforming to this guidance document must apply to amend the document so those products containing methidathion may be registered and reregistered under this guidance package. Mixtures and end-use products containing methidathion may not be registered or reregistered under this guidance package. However, the use patterns of the end-use products are considered for purposes of determining generic data requirements for methidathion.

2. Valid data for the manufacturing use described within this guidance package, that were submitted before the time of publication, do not meet or exceed the risk criteria listed in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations.

3. Registrants must provide or agree to develop the data as are specified in the tables within this guidance package in order to maintain existing registrations. New methidathion registrations must cite the data base described herein and are liable for the same data generation requirements as described for products undergoing reregistration.

4. Applications of the pesticide made in accordance with current use directions are not expected to result in residues of methidathion in excess of 400 parts per million (ppm) for citrus oil and 0.5 ppm for refined cottonseed oil. Combined residues of methidathion

and its metabolites, sulfoxide and sulfone, are not expected to exceed 0.06 ppm in meat, 0.025 ppm in milk, 0.10 ppm in poultry tissues and 0.05 ppm in eggs. Residues not exceeding these levels may enter interstate commerce. The Food and Drug Administration, DHHS, has been advised of these conclusions. The Agency will expeditiously move towards establishing Section 409 tolerances for citrus oil and refined cottonseed oil and Section 408 tolerances for meat, milk, poultry and eggs. Data on residues of cottonseed soapstock must be submitted in order to determine whether a food additive tolerance is needed for soapstock. The tolerances for residues of methidathion on almonds, walnuts and pecans established under Section 408 of FFDCA will be revoked by the Agency because they have been superseded by the existing group tolerance for nuts which was established on October 2, 1978.

D. Regulatory Rationale

The Agency has reviewed the available data concerning toxicology, environmental fate, residue and product chemistry, and ecological effects. Sufficient data are available to show that technical methidathion has a high acute oral and dermal toxicity to mammals and is assigned to Toxicity Categories I and II, respectively. Acute intoxication signs characteristic of acetylcholinesterase poisoning were demonstrated by the data. No data were available to assess the acute inhalation toxicity of technical methidathion or the acute effects for the formulation intermediate products. Data on the technical product demonstrate a potential for slight eye and dermal irritation. However, testing on the manufacturing-use products is required to fulfill Agency data requirements. Data also demonstrate that methidathion is not an acute delayed neurotoxin.

The histopathology data in an oncogenicity study in mice (Barnett et al., 1980) indicated statistically significant increases in the frequency of hepatocellular carcinomas and hepatocellular adenomas in male mice at the high dose level (100 ppm). However, this study, conducted by Industrial Bio-Test Laboratories, is deficient in several important respects (related to the way in which the study was conducted) and has been determined to be invalid in a review carried out by Health Protection Branch, Health Canada. New oncogenicity studies, using the mouse and an additional species, preferably the rat, are required.*_/

*_/ These studies are being voluntarily initiated by Ciba-Geigy due to the fact that Canada found the IBT mouse oncogenicity study to be invalid. The mouse study was begun in November, 1982, and the rat study will start in the first quarter of 1983. Interim reports will be available in early 1984 and final reports in 1986.

Ordinarily, a finding of potential oncogenicity in chronic effects testing could lead to the initiation of a "Rebuttable Presumption Against Registration" (RPAR) in order to weigh the risk of continued use against the benefits of that use. However, Section 3(c)(8) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) directs the Agency not to initiate a Rebuttable Presumption Against Registration action, unless a validated test or other significant evidence indicates prudent concerns of unreasonable adverse risk to man or the environment. Because the mouse oncogenicity study was found invalid in the IBT review by Canada, the most appropriate regulatory action is to move expeditiously in filling the data gaps.

Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires that tolerances be established for any pesticide residues concentrating in processed foods/feeds. A review of the residue data showed that there are finite residues of methidathion in citrus oils and refined cottonseed oil. While tolerances have been established under Section 408 of the FFDCA for methidathion residues in or on citrus and cottonseed as raw agricultural commodities (RAC), no Section 409 food additive tolerances exist for citrus oil or refined cottonseed oil. Citrus oil or refined cottonseed oil containing any residues exceeding the RAC tolerances could be seized as "adulterated food" by the Food and Drug Administration in the absence of such tolerances.

At the time the tolerance was established for cottonseed, a 409 tolerance was not needed because methidathion was approved for use on cotton before the bolls were open and the residue data indicated that the residues in the oil were lower than the residues in the cottonseed. Later, however, the use of methidathion on open cotton bolls was granted resulting in greater linter and seed exposure and oil residues which are higher than the cottonseed residues. The Agency should have required a 409 tolerance for that use but apparently overlooked it through administrative error. Based on available data, a food additive tolerance of 0.5 ppm should be established for cottonseed oil. Data on residue levels in soapstock are needed to determine whether a food additive tolerance is needed.

When RAC tolerances were established for citrus, a food additive tolerance was not set for citrus oils because it was thought that these oils were used at such low concentrations as flavoring agents that any residues in the final flavored food would be below the tolerance for citrus and probably at non-detectable levels. However, in 1978 this policy was questioned in connection with the chlorobenzilate RPAR. The Agency changed the policy in 1978 for several reasons: (1) citrus oils shipped interstate could be seized by FDA if residues exceed the RAC tolerance for citrus; (2) food additive tolerances had been previously set for mint oil, which is used at low concentrations as a flavoring agent; and

(3) a number of food additive tolerances had been established for various spices, which are also used at low levels as flavoring agents. Now the policy is to require data for cold pressed citrus oils and to establish a food additive tolerance when residues on the oils exceed the RAC tolerance for citrus. Because residues of methidathion in citrus oils (400 ppm) exceed the RAC tolerance (2 ppm), a food additive tolerance is needed.

In addition to these food additive tolerances, tolerances for meat, milk, poultry tissues and eggs need to be established. A review of existing data indicates that residues of methidathion and its metabolites, sulfoxide and sulfone, are not likely to exceed 0.06 ppm in meat, 0.025 ppm in milk, 0.10 ppm in poultry tissues and 0.05 ppm in eggs.

To bring the tolerances in line with current policies and to avoid the potential for seizure by FDA of legally treated commodities, the Agency will move expeditiously to establish food additive tolerances for citrus oils and cottonseed oil and to establish tolerances for meat, milk, poultry tissues and eggs.

Since the Agency is concerned about the indication of oncogenicity in the IBT mouse study, we intend to set an expiration date for the above tolerances of five years. This time period will allow the oncogenicity studies to be submitted and reviewed by the Agency in conjunction with the entire toxicological data base to determine if the food additive tolerances should be continued. In the interim, the Agency is establishing maximum residue limits for citrus oils, cottonseed oils and meat, milk, poultry tissues and eggs as specified above. The Agency is notifying the FDA that commodities containing these residue levels are acceptable and should not be seized. In addition, the Agency will evaluate any petitions for new or increased tolerances carefully to assure that the incremental residue contribution is insignificant.

The available methidathion environmental fate data are insufficient to fully assess this chemical at this time. However, from the available information, methidathion does not appear to represent an environmental hazard based on its current use pattern. It degrades fairly rapidly in the soil with a half-life of about 14 days and has a low bioaccumulation potential. Photodegradation should be a minor degradation pathway under natural conditions. Unaged residues are slightly mobile in medium to fine textured soils and immobile in organic soils. Both aged and unaged residues are mobile in coarse textured soils. The rapid degradation of methidathion in soil appears to mediate its potential to contaminate ground water in coarse textured soils.

Available data concerning the ecological effects of technical methidathion suggest a very high toxicity to fish and honey bees, and moderate toxicity to birds. The formulated product indicates slight toxicity to waterfowl. However, the available information is not sufficient to fully assess the hazard to wildlife. The existence of an aquatic hazard from methidathion leaching in sandy soil and sandy loam soil has not been assessed. This type of soil is found in some citrus regions near aquatic environments.

The Pesticide Incident Monitoring System (PIMS) report from 1966 through April, 1981, contained 38 reports of human poisoning and environmental effects involving methidathion, the majority of which involved methidathion alone, as opposed to being used with other chemicals in tank mixes. A consistent pattern of hazard associated with the recommended use of methidathion was not demonstrated. The majority of the cases of human poisoning appeared to be the result of misuse or accident.

Human exposure can occur during mixing, loading, handling, application and reentry operations. While data are not available to fully assess the potential for exposure of humans and non-target organisms to methidathion, the acute toxicity of methidathion is high enough to meet the guidelines criteria (Subdivision K) for requiring reentry data. Until the required data are submitted and a permanent reentry interval can be set, Agency policy requires that a 24-hour, interim reentry interval be set for this compound. A permanent reentry interval will be established after the data are submitted and reviewed. While this reentry interval will be required as a minimum standard for all states, any state may set more stringent requirements based on local needs and special conditions. For example, the State of California has set reentry intervals of 30 days for citrus and 2 days for all other crops.

In summary, the Agency has concluded that it should continue the registration for this chemical for the following reasons:

1. None of the studies reviewed by the Agency are sufficient to raise prudent concerns of unreasonable adverse risk to man or the environment. The Agency has thus concluded that the known risks, as mitigated by product labeling, are not adequate to warrant additional regulatory action at this time.

2. In accordance with the FIFRA, the Agency's policy is not to cancel or to withhold registration merely for the lack of certain data (See sections 3(c)(2)(B) and 3(c)(7) of FIFRA). Rather, publication of this guidance package provides a mechanism for identifying data needs, and reregistration under this document allows for upgrading of labels during the period in which the required data are being generated. When these data are received, they will be reviewed by the Agency. The Agency will then determine whether these data will affect the registration of this chemical.

3. The Agency has established that applications made in accordance with current labels are not expected to result in residues of methidathion and its metabolites in citrus oils or refined cottonseed oil in excess of 400 and 0.5 ppm, respectively. Residues are not expected to exceed 0.06 ppm in meat, 0.025 ppm in milk, 0.10 ppm in poultry tissues and 0.05 ppm in eggs. Levels not exceeding these amounts are acceptable and may enter interstate commerce. The Food and Drug Administration, DHHS, has been advised of this action. When required tolerance petitions are submitted, tolerances will be established for these residues. However, these tolerances will be in effect only five years so that the Agency can evaluate the required oncogenicity studies and determine if the tolerances should be continued in effect.

E. Criteria for Registration Under This Guidance Package

To be subject to this standard, products must meet the following conditions:

- contain methidathion as the sole active ingredient, and
- conform to the acute toxicity limits, product composition and use pattern requirements as discussed in the section which follows.

An applicant for registration or reregistration of products subject to this guidance package must comply with all terms and conditions described in this document, including a commitment to fill data gaps on a time schedule specified by the Agency and, when applicable, offering to pay compensation to the extent required by 3(c)(1)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. a136(c)(1)(D). Applicants for registration under this guidance package must follow the instructions contained within this document and complete and submit the appropriate forms within the time specified.

1. Product Composition Standard

For manufacturing-use products to be eligible for registration/reregistration under this standard, technical products must contain at least 95 percent methidathion and formulation intermediate products must contain between 50 and 60 percent methidathion as the sole active ingredient. Each product formulation proposed for registration must be fully described with an appropriate certification of limits.

2. Acute Toxicity Limits

The Agency will consider registration/reregistration of manufacturing use products containing methidathion regardless of the toxicity category, provided that the labeling of such products bears appropriate precautionary statements.

3. Use Patterns

To be registered under this standard, manufacturing-use products containing methidathion must be labeled to allow for formulation only into end use products, which are intended for non-domestic, terrestrial food crop uses, which includes alfalfa (including alfalfa hay, clover, clover hay, grass, and grass hay), almond hulls, artichokes, cotton, grapefruit, lemons, mangoes, nuts (including almonds, pecans and walnuts), olives, oranges, pome fruits (including apples and pears), potatoes, safflower, sorghum (fodder, forage and grain), stone fruits (including apricots, cherries, nectarines, peaches, plums and prunes), sunflower and tobacco. The attached index entry lists all registered uses for end-use products, which may be formulated from the manufacturing-use products covered by this guidance package, as well as approved maximum application rates and frequency.

F. REQUIRED LABELING

All manufacturing-use products containing methidathion must bear appropriate labeling as specified in 40 CFR 162.10. Other portions of this guidance package contain specific information regarding label requirements.

In addition, the following specific labeling requirements apply to technical and manufacturing-use products:

1. Use Pattern Statements

"For formulation into end-use insecticide/miticide products intended only for uses accepted by the United States Environmental Protection Agency."

2. Human Hazard Precautionary Statements

"Causes cholinesterase inhibition. Atropine is antidotal. 2 PAM is also antidotal and may be administered in conjunction with atropine. Warning symptoms of cholinesterase inhibition include weakness, headache, tightness in the chest, blurred vision, nonreactive pinpoint pupils, salivation, sweating, nausea, vomiting, diarrhea and abdominal cramps."

The registrant may submit an alternative antidote statement for Agency consideration.

3. Environmental Hazard Statements

"This pesticide is toxic to birds and fish. Do not discharge into lakes, streams, ponds, or public water unless in accordance with an NPDES permit. For guidance contact your Regional Office of the United States Environmental Protection Agency."

G. TOLERANCE REASSESSMENT

Tolerances have been established for methidathion on a number of different food and forage crops and current residue data are adequate to support these tolerances. However, a tolerance proposal for combined residues of methidathion and its metabolites (sulfoxide and sulfone) is needed for milk, meat, poultry tissues and eggs. A petition for tolerance (under Section 409 of the FFDCA) must also be submitted so that food additive tolerances may be established for citrus and cottonseed oils. Residue data on cotton soapstock must also be submitted. In the interim, levels of 400 ppm and 0.5 ppm for citrus oils and refined cottonseed oil, respectively, are acceptable to the Agency for entering interstate commerce. A proposal for an increase in the tolerance level for alfalfa is currently pending review.

The Acceptable Daily Intake (ADI) was originally set using a two-year dog cholinesterase no observed effect level (NOEL) of 4 ppm (0.100 mg/kg). A ten fold safety factor was used, and the percent ADI occupied was calculated to be 20.31 (Johnston, 1967, MRID 00011839).

The Agency has since reevaluated the ADI based on the dog chronic feeding study (Johnston, 1967, MRID 00011839) and has now determined that the cholinesterase NOEL is 16 ppm. A systemic NOEL (liver effects) of 4 ppm has been substantiated. Therefore, the Agency has changed the safety factor used in the ADI calculation from 10 to 100. Using the 100 fold safety factor the recalculated ADI is 0.0010 mg/kg/day (Coberly, 1981, GS0034012), with a maximum permissible intake (MPI) of 0.0600 mg/day for a 60 kg individual. The current theoretical maximum residue concentration (TMRC) for methidathion based on established tolerances is 0.1219 mg/day for a 1.5 kg diet. Therefore, the theoretical percent occupied ADI is 203 [Table 1, Column A].

While the theoretical percent ADI occupied for methidathion is greater than 100 percent, the percent occupied ADI is artificially high because the percent ADI calculation assumes that residues on all registered crops are at tolerance level and that 100 per cent of each crop is treated with methidathion.
In order to establish actual exposure, the Agency has reexamined available residue data on citrus, which is the major use site for methidathion. In addition, the Agency has calculated the potential contributions of methidathion residues from citrus oils, cottonseed oil, meat, milk, poultry tissues and eggs because tolerances are needed, but have not been established, for these food items. The results of these calculations are shown in Table 1. A detailed discussion follows.

Table 1. Percent of Acceptable Daily Intake Occupied Based on Calculations of Methidathion Residues in Food

TMRC Based on Established Tolerances (A)	Adjusted Residue Calculation Based on Actual Residues In Citrus Juice and Pulp (B)	TMRC Based on Established Tolerances Plus Citrus Oil and Cotton-Seed Oil Residues (C)	Adjusted Residue Calculation (B) Plus Citrus Oil and Cottonseed Oil Residues (D)	Adjusted Residue Calculation (B) Plus Citrus Oil and Cotton-Seed Oil Residues Corrected for Percent Crop Treated (E)	Adjusted Residue Calculation (B) Plus Citrus Oil and Cotton-Seed Oil Residues Corrected for Percent Crop Treated Projected Into 1986 (F)	TMRC Based on Established Tolerances Plus Citrus Oil, Cotton-Seed Oil and Meat, Milk, Poultry and Eggs (G)	Adjusted Residue Calculation (E) Plus Meat, Milk, Poultry and Eggs (H)
203	53.2	333	152	64	72	378	109

The residue chemistry data for citrus indicate that the majority of residues in oranges, lemons, and grapefruit are contained in the peel, as opposed to the juice and pulp. The tolerance for whole oranges, lemons, and grapefruit is 2 ppm. However, these data indicate that a more realistic maximum residue of methidathion in juice is 0.2 ppm and in pulp is 0.2 ppm. Using this revised 0.2 ppm for oranges, lemons and grapefruit, the TMRC and the percent ADI used have been recalculated. The adjusted residue calculation is therefore 0.0319 mg/day and the percent ADI occupied is 53.2 [Table 1, Column B].

The potential contribution to the diet of residues of methidathion found in cottonseed oil and citrus oil has been evaluated as follows. Although food additive tolerances are not established for these processed foods, the Agency is required by Section 409 of the FFDCA to do so. Using a food factor of 0.2% and a tolerance level of 0.5 ppm, the Agency estimates that refined cottonseed oil could contribute 2.5% of the ADI. Using a tolerance level of 400 ppm methidathion in citrus oils and a food factor of 0.013%, the Agency calculates that citrus oils residues could contribute 127% of the ADI. Adding these residue contributions to the TMRC discussed above (0.1219 mg/day) results in a 333% occupied ADI (203% + 2.5% + 127%) [Table 1, Column C]. However, adding the citrus oils and refined cottonseed oil residues to the adjusted residue calculation mentioned above 0.0319 mg/day) results in a 152% occupied ADI (53.2% + 2.5% + 127%) [Table 1, Column D].

Because the latter adjusted residue calculation still exceeds the ADI, the Agency has estimated actual potential residues from citrus oils and refined cottonseed oil by taking into account the percent of crop actually treated. For cotton, it is estimated that only 1% of the crop is treated. For citrus, the estimated percent crop treated is as follows: oranges=8%, grapefruits=8%, lemons=11%, limes=unknown. Using these figures, the potential contribution of cottonseed oil to the ADI is 0.025% and the contribution of citrus oils to the ADI is 10.3%. Adding these contributions to the adjusted residue caclulation of 0.0319 mg/day results in only 64% of the ADI occupied [Table 1, Column E].

To estimate residues which might occur in the future, the Agency has projected that by 1986 the precent crop treated for citrus would not exceed 15% and for cotton would not exceed 5%. Using these projections, the contributions to the ADI would be 19% for citrus oils and 0.12% for refined cottonseed oil, resulting in a percent occupied ADI of 72 (53.2% + 19% + 0.12%) [Table 1, Column F].

Finally, the potential residue contribution from meat, milk, poultry tissues and eggs has been estimated as 45% of the ADI, based on maximum expected residues of 0.06 ppm in meat, 0.025 ppm in milk, 0.10 ppm in poultry tissues and 0.05 ppm in eggs. When this contribution is added to the TMRC in column C of Table 1, the TMRC becomes 378% of the ADI [Table 1, Column G]. However, when the potential contribution of residues from meat, milk, poultry tissues and eggs is added to the estimated actual residues resulting from treated crops, citrus oils and refined cottonseed oil [Table 1, Column E], the resulting occupied ADI is 109% [Table 1, Column H].

In summary, the TMRC, a theoretical estimate that assumes maximum possible residues and 100% of crops are treated, exceeds the ADI. However, the current and estimated actual residues of methidathion are expected to result in a residue burden which is slightly above the ADI. The Agency has determined that the residues from established tolerances, citrus oils, refined cottonseed oil, meat, milk, poultry tissues and eggs are acceptable. The Agency has also notified the Food and Drug Administration that levels of methidathion found in interstate commerce not exceeding 400 ppm for citrus oils, 0.5 ppm for refined cottonseed oil, 0.06 ppm for meat, 0.025 ppm for milk, 0.10 for poultry tissues and 0.05 ppm for eggs are acceptable. The Agency will move expeditiously to establish tolerances for a period not to exceed five years so that the required oncogenicity studies and the entire data base may be reevaluated and a determination to be made whether to continue these tolerances. In the interim, the Agency will carefully review any petitions for new or increased tolerances to assure the protection of public health. Because significant data gaps exist, the Agency will not approve new food uses unless the incremental residue contribution is insignificant.

III. DATA COMPENSATION

As part of your application for reregistration, you must comply with the data requirements of FIFRA Section 3(c)(1)(D) by including with your application a completed Data Compensation Statement (Appendix III-1). That form includes:

A. A statement that you offer to pay compensation to other persons with regard to the application to the extent required by FIFRA Sections 3(c)(1)(D) and 3(c)(2)(D).

B. A statement acknowledging that if EPA approves your application for registration, the approval will be based on EPA's consideration of the following:

1. All the existing "generic" data* which, according to the table, "Generic Data Requirements for Manufacturing Use and End Use Products" (Table A at the end of Section IV), is relevant to EPA's evaluation of the registrability of your product (taking into account your product's composition

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*/ Generic data pertain to the properties or effects of a particular ingredient, and thus is relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

and formulation category, and the uses of your product which its label will permit).

2. The "product-specific" data* which you have listed on the form entitled "Product-Specific Data Report" (Appendix III-2).

C. A statement that you have furnished an offer to pay compensation to the person(s) listed below in the manner specified:

1. Persons to whom offers must be made: An offer must be furnished to each person who was the original submitter of any of the generic or product specific data upon which approval of your application will be based, except that:

   a. You need not furnish an offer with respect to data that were originally submitted prior to January 1, 1970.

   b. FIFRA Section 3(c)(2)(D) provides that you need not furnish an offer with respect to any "generic" data, _if_ your product is an end-use product and _if_ its active ingredient will be present in your product solely because of the incorporation into your product of another registered manufacturing-use product which contains that active ingredient and which you purchase from another producer.

Note: This exemption does not cover "product-specific" data.

c. Many data submitters have informed EPA that they do not wish to receive offers under FIFRA Section 3(c)(1)(D). The various persons who submitted data listed in the bibliography (Appendix III-3) who have not waived their rights to receive offers will be listed in Table A, B, or C. You will be required to write those companies if the data in those tables are required to support your formulations and uses.

d. You need not furnish an offer to any person with whom you have already agreed in writing concerning the amount (if any) and terms of compensation payable under FIFRA Section 3(c)(1)(D) in connection with the reregistration of your product.

e. You need not furnish an offer with respect to any data unless the data were submitted to EPA (or its predecessor agencies) to support an application for registration, amended registration, or reregistration; to support or maintain in effect an existing registration; to support an application for an experimental use permit; or to support a petition for a tolerance, food additive regulation, or other clearance under the Federal Food, Drug and Cosmetic Act which was a prerequisite to a FIFRA registration action.

2. Form of the offer: You must furnish each person who is entitled to receive an offer the following information, in writing:

   a. A notification of your intent to apply for reregistration under this guidance document, and the name, active ingredient, and intended uses of your product.

   b. An offer to pay the person compensation, with respect to approval of your application, to the extent required by FIFRA Sections 3(c)(1)(D) and 3(c)(2)(D), and an offer to begin negotiations to set the amount and terms of compensation.

c. Your name, mailing address, and telephone number.

IV. REQUIREMENT FOR SUBMISSION OF GENERIC DATA UNDER FIFRA SECTION 3(c)(2)(B)

A. This portion of the Guidance Document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B). EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this Guidance Document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. Entitlement of Certain End-Use Registrants to an Exemption. Under the circumstances described in this Section III(B), EPA will refrain from suspending the registration of an end-use product even if its registrant does not submit data in response to this Notice. EPA's position is based on the intent of Congress as set forth in FIFRA Section 3(c)(2)(D). Under that section, if generic data on an active ingredient had already been submitted to EPA, an applicant for registration of an end-use product would be excused from the normal Section 3(c)(1)(D) requirement of submitting or citing, and offering to pay compensation for, those data as a condition of obtaining registration. To qualify for that exemption, the active ingredient must be present in her/his product solely as a result of her/his incorporation into her/his product (during formulation or packaging) of a manufacturing-use product containing that active ingredient registered under FIFRA and purchased from another producer. The object of this provision is to simplify data compensation by making compensation for the generic data on the active ingredient an element of the market cost of registered manufacturing-use products, so that formulators or other registrants who purchase such products need not separately offer to pay for data on the active ingredient.

EPA has concluded that these principles should also apply in the closely analogous situation presented by this Section 3(c)(2)(B) requirement. However, principles of fairness to those who incur expenses of data generation and submission make it necessary to ensure that a registrant be exempted from this data submission requirement only if the active ingredient in her/ his product is being purchased from a firm which is required to submit (or to offer to share in the cost of obtaining) the generic data required by this Notice.

If a registrant who is subject to this Section 3(c)(2)(B) Notice fails to comply with the data submission requirement, the Administrator may suspend her/his registration. However, this authority is discretionary, and the Administrator will not exercise it to suspend a registration if:

1. the registration is for an end-use product, as opposed to a manufacturing-use product; and

2. the active ingredient in the end-use product is present solely as the result of the incorporation into that product (during formulation or packaging) of a manufacturing product which contains that active ingredient, is registered under FIFRA, and is purchased by the registrant; and

3. the registrant completes and executes a "Generic Data Exemption Statement" (Appendix IV-1) for the

end-use products, and submits it to EPA within 90 days of receipt of this Notice; and

4. one or more registrants actually do undertake to submit, and do submit, all the data required by this Notice.

C. What Generic Data Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this section. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA approved protocols, The Pesticide Registration Guidelines,*/ or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD), which are yet to be published. If you wish not to develop data which are necessary to support the continued registration of certain uses appearing in your current labeling, you may delete those uses at the time you submit your revised labeling for registration.

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*/ The Pesticide Registration Guidelines were proposed in two separate publications. On July 10,1978, EPA issued proposed guidelines for product chemistry, environmental chemistry, and fish and wildlife hazard testing, 43 FR 29696. The Agency published proposed human hazard guidelines on August 22, 1978, 43 FR 37336.

Also for certain kinds of testing (generally Ecological Effects), EPA requires the test substance to be a "typical formulation," and that in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.). These are classified as generic-data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data which are required on each formulation, regardless of type of formulation. Product-specific data are further explained under Section IV of this document and are specified in Tables B and C at the end of this Section.

D. Options Available for Complying with Requirements to Submit Data.

You must submit to EPA within 90 days of your receipt of this Notice a completed copy of the form entitled

"FIFRA § 3(c)(2)(B) Summary Sheet" (Appendix IV-2) for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. Attach a completed "Generic Data Exemption Statement" (Appendix IV-1).

2. (a) Notify EPA that you will submit the data, and (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

3. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option you must at the same time notify EPA which registrant(s) are parties to the agreement. At least one of the

parties to the agreement must respond to this Notice in the manner specified by paragraph III (D)(1) above.

4. File with EPA a completed "Statement of Willingness to Enter Into an Agreement with Other Registrants for Development of Data," (Appendix IV-3*/.

5. Request that EPA amend your registration by deleting the uses for which the data are needed.

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data, or a cost-sharing agreement between all such registrants, is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if: (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)], and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

6. Request voluntary cancellation of the registration(s) of your products for which the data are needed.

E. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted.

If the test procedures you plan to use deviate from (or are not specified in) registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you want, or think that you will need, more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. In the meantime, you must strive to meet the deadline for submitting the required data while EPA considers your request.

DATA REQUIREMENTS CHART A

Methidathion

Generic Data Requirements: PRODUCT CHEMISTRY*

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? 1/
§158.120	Product Chemistry				
61-1	Product Identity & Disclosure of Ingredients	Technical Grade (TG)	yes	000011347, 000012645 000012528	no
61-2	Description of Manufacturing Process	TG	yes	000011347, 005016154	no
61-3	Discussion on Formation of Unintentional Ingredients	TG	partially 2/	000011347	yes
62-1 and 62-2	Declaration & Certification of Ingredients Limits	TG	partially 2/	000011347	yes
62-3	Analytical Methods to Verify Certified Limits	TG	partially 3/	000011348, 000011930 000011414, 000011854	yes
63-2	Color	TG	yes	000011347, 000012645	no
63-3	Physical State	TG	yes	000011347, 000012645	no
63-4	Odor	TG	yes	000011347, 000012645	no
63-5	Melting Point	TG	yes	000011347, 000012645	no
63-6	Boiling point	TG	yes	000011347, 000012645	no
63-7	Density, Bulk Density, or Specific Gravity	TG	partially 4/	000011347, 000012645	yes
63-8 63-9	Solubility Vapor pressure	TG	yes	000011347, 000012645	no
63-11	Octanol/Water Partition Coefficient	TG	no	-	yes
63-12	pH	TG	no	-	yes
63-13	Stability	TG	yes	000011347, 000012645	no

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*All data requirements must be fulfilled by each applicant, and data from other applicants may not be cited. Therefore, even if the chart indicates that a data requirement has been partially or completely fulfilled, except for 64-3, these requirements must be filled at the time of registration or reregistration.

FOOTNOTES-- CHART A P [illegible] CHEMI[illegible]

1/ . data must be submitted within [illegible]ths.

2/ 0.0-0.8% remains unaccounted for as unknowns. The presence of unknown material should be explained. The possible formation of nitrosamines and other compounds in the technical, manufacturing and end-use products should be discussed.

3/ The actual analytical data of the various batches are still needed.

4/ The guidelines state that the solubility data should be expressed in terms of g/100 ml of solvent at 20°C (68°F or in terms such as ppm (mg/kg)). It was reported at 25°C. This is acceptable, however, the agency needs to know whether the percentage solubility is based on the solution or the solvent.

DATA REQUIREMENTS CHART A

Methidathion

Generic Data Requirements: RESIDUE CHEMISTRY

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)?[1]
§158.125 Residue Chemistry					
-	Metabolism in Plants	Radiolabeled Active Ingredient	partially[2]	005011885, 000011317 000022911, 005011162 005012174, 000060995 000022910, 000022905 000022907	yes
-	Metabolism in Animals	Radiolabeled Active Ingredient	yes	000026090, 000011936 000022908, 000011283 000011848, 000011314 000022909	no
-	Analytical Methods	Analytical Grade of Active Ingredient	partially[3]	000011326, 005011904 000011334, 000011337 000020944, 000011320 000011324, 000020945 000029229, 000020979	yes
-	Residue Data: Crops Alfalfa (including hay, clover, clover hay, grass and grass hay)	Representative Formulation (RF)	yes[4]	000011318, 000011319 000011321, 000011340 000012575	no
	Almonds, hulls		yes	000036942, 000020946	no
	Artichokes		yes[2]	000011764	yes[2]
	Citrus Oil		partially[5]	000011323	yes
	Cottonseed		partially[6]	000011786, 000011325	yes
	Grapefruit		yes	000029215, 000011323 000060899	no
	Lemons		yes	000011422	no
	Mangoes		yes	000011474	no
	Nuts (including almonds, pecans and walnuts)		yes[7]	000020946, 000036942 000011640, GS0034014	no
	Olives		yes	000011456	no

DATA REQUIREMENTS CHART A continued

Methidathion

Generic Data Requirements: RESIDUE CHEMISTRY continued

Guide-lines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)?[1]
§158.125	Residue Chemistry (continued)				
–	Residue Data: Crops Continued				
	Oranges		yes	000029215, 000011321 000060899	no
	Pome Fruits (including apples and pears)		yes	000012593, 000020946	no
	Potatoes		yes	000014404	no
	Safflower		yes[8]	000038279	no
	Sorghum (fodder and forage)		yes	000011303	no
	Sorghum (grain)		yes	000011303	no
	Stone Fruits (including apricots, cherries, nectarines, peaches, plums and prunes)		yes	000012593, 000020946	no
	Sunflower		yes[9]	GS0034015	no
	Tobacco		yes	000011856	no
	Residue Data:				
	Milk and Meat	RP	yes[10]	000022574, 000078342	no[10]
	Poultry and Eggs	RP	yes[10]	000011314	no[10]
–	Storage Stability	RP	partially[11]	000020940	yes

FOOTNOTES--RESIDUE CHEMISTRY

1/ All data must be submitted within 48 months.

2/ Identification of water soluble metabolites in tomatoes is needed before a tolerance can be established. The same information is needed for artichokes, in order to raise the existing tolerance.

3/ A method tryout by the Agency for determining the residues of sulfoxide (GS 28370), sulfone (GS 28369), and the oxygen analog (GS 13007) in meat, milk, poultry and eggs is needed. GLC recovery data for the oxygen analog are needed for method validation of AG 334 (MRID 00020944).

4/ The current tolerances for these crops are supported. However, the proposed increase in tolerance for alfalfa from 6 to 12 ppm is currently in review.

5/ A proposal for a food additive tolerance is needed.

6/ Fractionation data are needed for soapstock. A proposal for a food additive tolerance of 0.5 ppm is needed for refined cottonseed oil.

7/ The established tolerances for residues of methidathion on almonds, walnuts and pecans need to be revoked by the Agency in view of the existing group tolerance for nuts.

8/ Data on meal and seed fractions of sunflower seed translated to safflower indicate that methidathion will not concentrate in any specific fraction of safflower seed, and therefore no food additive tolerance for safflower meal and oil is needed.

9/ Since the residues of methidathion in the oil are lower than the sunflower seed, no food additive tolerance is required.

10/ Sufficient residue data are available to support tolerances for combined residues of methidathion and its metabolites sulfoxide and sulfone in milk, meat, poultry and eggs. However, a tolerance proposal in terms of combined residues of the parent compound and its metabolites sulfoxide and sulfone is still needed.

11/ Data on the storage stability of residues in spiked samples are needed.

DATA [illegible]MENTS CHART A

Methidathion

Generic Data Requirements: ENVIRONMENTAL FATE

Guidelines Citation	Name of Test	Composition	Use Pattern[1]	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)?[11]
§158.130 Environmental Fate						
161-1	Hydrolysis	2/	A	no	-	yes
161-2	Photodegradation in Water	2/	A	no	-	yes
161-3	Photodegadation in Soil	2/	A	partially[4]	005021793	yes
161-4	Photodegradation in Air	2/	A	no	-	reserved[5]
162-1	Aerobic Soil	2/	A	yes	000011317, 000011327 005011889	no
162-2	Anaerobic Soil	2/	A	no	-	yes
-	Microbiological	-	-	-	-	reserved[6]
163-1	Leaching	2/	A	partially[7]	000011833, 005021425 000011403	yes
163-2	Laboratory Volatility	3/	A	no	-	yes
163-3	Field Volatility	3/	A	no	-	reserved[5]
164-1	Field Dissipation-Terrestrial	3/	A	yes	000011827, 000011828 000011826, 005011895 005011904, 005015398	no
164-5	Dissipation-Long Term Studies	3/	A	8/	-	-

DATA REQU[illegible] CH

Meth[illegible]ion

Generic Data Requirements: ENVIRONMENTAL FATE continued

Guide-lines Citation	Name of Test	Composition	Use Pattern 1/	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? 11/
§158.130 Environmental Fate (continued)						
165-1	Confined Accumulation-Rotational Crops	3/	A	no	-	yes
165-2	Field Accumulation-Rotational Crops	3/	A	no	-	yes
165-4	Fish Accumulation-Laboratory Studies	2/	A	no 9/	000011405	yes
165-5	Field Accumulation-Aquatic Non-Target	3/	A	no	-	yes
Subpart K	Reentry	3/	A	no 10/	005007864, 005011892	yes

FOOTNOTES--ENVIRONMENTAL FATE

1/ This column specifies the use sites for which the data are required. The code A refers to nondomestic, terrestrial, food crop, which includes field and vegetable crops, and orchard/citrus/tree fruit crops. However, Anaerobic soil metabolism (158.26-162-2), Confined accumulation-rotational crops (158.26-165-1), and Field accumulation-rotational crops (158.26-165-2) need only be fulfilled for nondomestic, terrestrial field and vegetable crops.

2/ The material used should be radiolabeled analytical grade or non-labeled technical grade.

3/ The material used should be an end-use product representative of the major formulation category.

4/ Additional data using four or more sampling intervals with dark controls are needed. A soil appropriate to an application site must also be used.

5/ The requirement for the submission of these data is reserved, pending the data derived from the laboratory volatility studies required under Section 158.26-163-2.

6/ The requirement for the submission of these data is reserved, pending the receipt and modification of test protocols.

7/ Data are available concerning the mobility of methidathion aged residues in soil. However, leaching studies (unaged) are needed to fully assess the mobility in the soil.

8/ No data are required because data indicate that methidathion readily dissipates in a soil environment.

9/ This requirement may be waived, if the registrant can offer acceptable evidence showing that the active ingredient and/or its principal degradation product(s) will not reach water, or will not persist in water (i.e. a half-life of approximately 4 days or less) and has properties suggesting a relatively low potential for accumulation in fish (i.e. an octanol/water partition coefficient less than 1,000) or a lack of accumulation in the organs and tissues of mammals or birds.

10/ For each crop the registrant must propose an acceptable reentry interval; this proposed interval may be based on any of the following: a) existing state reentry intervals; b) data on dissipation of foliar residues (decline curve) and on human exposure to those residues; c) determination of that time beyond which there are no detectable foliar residues, under appropriate climatic conditions. (Note that the California Department of Food and Agriculture methidathion reentry intervals are 30 days for citrus and 48 hours for other crops.)

11/ All data must be submitted within 48 months.

DATA REQUIREMENTS CHART A

Methidathion

Generic Data Requirements: TOXICOLOGY

Guidelines Citation	Name of Test	Composition	Use Pattern[1]	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)?[2]
§158.135 Toxicology						
81-1	Acute Oral Toxicity	Technical Grade (TG)	A	yes	000012703, 000012726 GS0034001, 000011704 000012714, GS0034002	no
81-2	Acute Dermal Toxicity	TG	A	yes	GS0034003, GS0034004	no
81-3	Acute Inhalation Toxicity	TG	A	no[3]	-	yes
81-4	Primary Eye Irritation	TG	A	yes	GS0034010	no
81-5	Primary Dermal Irritation	TG	A	yes	GS0034011	no
81-6	Dermal Sensitization	TG	A	no	-	yes
81-7	Acute Delayed Neurotoxicity	TG	A	yes	000011704	no
82-1	Subchronic Oral Toxicity	TG	A	yes[4]	000011819, 000011839	no
82-2	21-Day Subchronic Dermal Toxicity	TG	A	no	-	yes
82-3	90-Day Subchronic Dermal Toxicity	TG	A	no[5]	-	no
82-4	Subchronic Inhalation	TG	A	no	-	reserved[6]
82-5	Subchronic Neurotoxicity	TG	A	no	-	no[7]
83-1	Chronic Toxicity - 2 spp. Rodent and Non-rodent	TG	A	yes	000011819, 000011839	no
83-2	Oncogenicity	TG	A	no[8]	-	yes
83-3	Teratogenicity	TG	A	partially[9]	GS0034009	yes

DATA REQUIREMENTS

Methidathion

Generic Data Requirements: TOXICOLOGY continued

Guidelines Citation	Name of Test	Composition	Use Pattern[1/]	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)?[2/]
§158.135 Toxicology (continued)						
83-4	Reproduction	TG	A	partially[10/]	000011840	yes
84-2 through 4	Mutagenicity	TG	A	yes[11/]	000078332, 000060642 000078329, 000078331 000011351, 000078334 000078330, 005020908 000078335, GS0034005 GS0034006, GS0034008	no[11/]
85-1	Metabolism	TG	A	yes[12/]	000026090, 005016720 000011451, 000011341 005011901, 005002409	no

FOOTNOTES--TOXICOL. ANT A

1/ This column specifies the use sites for wh the data are required. The code A refers to nonaquatic, terrestrial, food crop, which includes field and vegetable crops, and orchard/citrus/tree fruit crops.

2/ All acute toxicology data must be submitted in 12 months; all other toxicology data are due in 48 months.

3/ Testing is required unless evidence is submitted that technical methidathion cannot be released or utilized as a vapor or respirable aerosol (i.e., an aerosol with at least 20% of the particles having an aerodynamic equivalent diameter of less than 10 micrometers).

4/ The subchronic oral toxicity studies were not sufficient to satisfy this data requirement. However, since the chronic feeding studies (Johnston, 1967, MRID 00011839 and Coulston et al., 1971, MRID 00011819) are sufficient to meet the data requirement for chronic feeding studies, additional subchronic oral studies are not required.

5/ These data are not required, because methidathion's use does not involve purposeful application to the skin or result in comparable human exposure.

6/ A subchronic inhalation test may be required, pending the results of an acute inhalation test.

7/ Methidathion was shown to have no neurotoxic effect in hens up to a dose of 350 mg/kg (Sachsse et al., 1977, MRID 00011704). Therefore, subchronic neurotoxicity testing is not required.

8/ One mouse oncogenicity study (Barnett et al., 1980, MRID 00040654) was submitted. The results of the histopathology data demonstrated statistically significant increases in male mice of hepatocellular carcinomas (p<0.05) and hepatocellular adenomas (p<0.001) at the high dose level (100 ppm). However, this study was conducted by IBT (IBT #8560-09100) and upon audit, has been declared by Canada to be invalid (December 9, 1981). This study may, therefore, only be used as a reference study. Additional testing is required on the technical material in the mouse and in an additional species, preferably the rat.

9/ The study (Ciba-Geigy, Ltd., 1976, MRID GS0034009) which was reviewed is classified as core minimum. Methidathion was shown to have no teratogenic effects up to a dose of 5 m/kg/day, which was the highest dose tested. Testing is required in an additional species, preferably in an albino rabbit, using technical material.

10/ The study (Lobdell and Johnston, 1966, MRID 00011840) was classified as only supplementary. A 2-generation, 1 litter/generation test is required on the technical material.

11/ Based upon the available information, methidathion and its metabolites GS 12956, GS 28369 and GS 28370 are not considered to be mutagenic. Where marginal detectable activity was observed the biological relevance of the results were not clearly demonstrated. Further testing is not required at this time. However, the Agency requests that Ciba-Geigy submit the original data on nucleus anomaly tests of methidathion (Hool, 1980, MRID 00078134) and metabolite GS 12956 (Hool, 1980, MRID GS0034008) so that an in-depth analysis of these studies may be done. Pending the results of these evaluations, additional testing may be required.

12/ Based on the available information, there was no clear accumulation of methidathion in the tissues of rats and the metabolism and excretion of methidathion was almost complete in 48 hours (78% of the dose).

DATA REQUIREMENTS CHART B

Methidathion

Product-Specific Manufacturing-Use Data Requirements: PRODUCT CHEMISTRY*

Guidelines Citation §158.120 Product Chemistry	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? 1/
61-1	Product Identity & Disclosure of Ingredients	Each Product	yes	000011347	no
61-2	Description of Manufacturing Process	Each Product	no	-	yes
61-3	Discussion on Formulation of Unintentional Ingredients	Each Product	partially 2/	000011347	yes
62-1 and 62-2	Declaration & Certification of Ingredients Limits	Each Product	partially 2/	000011347	yes
62-3	Analytical Methods to Verify Certified Limits	Each Product	partially 3/	000011348, 000011930 000011854, 000011414	yes
63-3	Physical State	Each Product	yes	000011347	no
63-6	Boiling Point	Each Product	no	-	yes
63-7	Density, Bulk Density, or Specific Gravity	Each Product	no	-	yes
63-8	Solubility	Each Product	no	-	yes
63-12	pH	Each Product	no	-	yes
63-14	Oxiding/Reducing Action	Each Product	no	-	yes
63-15	Flammability	Each Product	no	-	yes
63-16	Explosiveness	Each Product	no	-	yes
63-17	Storage Stability	Each Product	no	-	yes
63-18	Viscosity	Each Product	no	-	yes
63-19	Miscibility	Each Product	no	-	yes
63-20	Corrosiveness	Each Product	no	-	yes

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*All data requirements must be fulfilled by each applicant, and data from other applicants may not be cited. Therefore, even if the chart indicates that a data requirement has been partially or completely fulfilled, except for 64-3, these data requirements must be fulfilled at the time of registration or reregistration.

FOOTNOTES--CHART B P [illegible]ISTRY

1/ All data must be submitted within 6 months.

2/ 0.0 - 0.9% remains unaccounted for as unknowns. The presence of unknown material should be explained. The possible formation of nitrosamines and other compounds in the technical, manufacturing and end-use products must be discussed.

3/ The actual analytical data of the various batches are still needed.

DATA REQUIREMENT CHART B

Methidathion

Product-Specific Manufacturing-Use Data Requirements: TOXICOLOGY

Guidelines Citation §158.135 Toxicology	Name of Test	Composition	Use Pattern[1]	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)?[2]
81-1	Acute Oral Toxicity	Each Product	A	no[3]	-	yes
81-2	Acute Dermal Toxicity	Each Product	A	no[3]	-	yes
81-3	Acute Inhalation Toxicity	Each Product	A	no	-	yes
81-4	Primary Eye Irritation	Each Product	A	no[3]	-	yes
81-5	Primary Dermal Irritation	Each Product	A	no[3]	-	yes
81-6	Dermal Sensitization	Each Product	A	no	-	yes

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[1] This column specifies the use sites for which the data are required. The code A refers to nondomestic, terrestrial, food crop, which includes field and vegetable crops, and orchard/citrus/tree fruit crops.

[2] All data must be submitted within 12 months.

[3] The available data were generated from the technical grade. (See Chart A for Generic Data Requirements: Toxicology). This satisfies these requirements for the technical, but not for the formulation intermediate products.

DATA REQUIR [illegible] A

Methidathion

Generic Data Requirements: ECOLOGICAL EFFECTS

Guidelines Citation	Name of Test	Composition	Use Pattern[1]	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)?[2]
§158.145 Wildlife and Aquatic Organisms						
71-1	Avian Single-Dose Oral LD_{50}	Technical Grade (TG)	A	no	-	yes
71-2	Avian Dietary LC_{50}	TG	A	yes	000011944, 000011841	no
72-1	Fish Acute LC_{50}	TG	A	partially[3]	00011841	yes
72-2	Acute Toxicity to Aquatic Invertebrates	TG	A	yes	000011350	no
72-3	Acute Toxicity to Estuarine & Marine Organisms	TG	A	no[4]	-	yes .

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[1] This column specifies the use sites for which the data are required. The code A refers to nondomestic, terrestrial, food crops, which include field and vegetable crops, and orchard/citrus/tree fruit crops. Registration for other use patterns may involve different data requirements.

[2] All data must be submitted within 48 months.

[3] The data which was submitted has several deviations from the acceptable requirement, which include use of improper species of fish (goldfish), lack of water quality data and indication that portions of all studies were conducted at different times.

[4] Data are required for establishing the acute toxicity of the technical pesticide to estuarine marine invertebrates, when the end-use product is expected to enter the estuarine or marine environment in significant concentrations because of its mobility pattern. Methidathion is mobile in sandy soil and sandy loam soil, which are the characteristic soil types for citrus, cotton and artichokes. These crops are grown in coastal regions.

V. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA UNDER FIFRA § 3(c)(2)(B)

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B) EPA has determined that you must submit these data to EPA in order to maintain the registration of your product(s). All these data must be submitted not later than 6 months after you receive this Guidance Document.

The tables entitled "Product-Specific Data Requirements for Manufacturing-Use Products" and "Product-Specific Data Requirements for End-Use Products," which appear as Tables B and C of this Guidance Document, permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Most Data Be Submitted Under § 3(c)(2)(B)?"

In some cases the Tables may note that EPA already possesses some or all of the product-specific data needed to evaluate your product; if that is the case, we encourage you to elect to cite that data in lieu of generating and submitting new data. (You must comply with FIFRA Section 3(c)(1)(D) if you elect to cite existing data; see Section III of this Guidance Document.)

VI. LABELING, CLASSIFICATION, AND PACKAGING INFORMATION

The Agency requires applicants for registration to amend their product's labeling to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application for reregistration, you must submit draft labeling revised to be consistent with: your product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.1], as indicated by the following paragraphs of this section of the Guidance Document. The labeling must be submitted within 6 months of your receipt of this Guidance Document.

If you fail to submit revised labeling and packaging information complying with this section, EPA will issue a notice of intent to cancel your registration under FIFRA § 6(b)(1).

A. Label Contents

40 CFR Section 162.10 (Appendix VI-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to

as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix VI-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix VI-1. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix VI-1. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net content must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix VI-1. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix VI-1. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix VI-1. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix VI-1. [40 CFR §162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various sized labels, as set forth in the Regulations. It should be noted that labeling regulations now being drafted require a minimum 8 point (3 mm) type size for all print on a label. When the guidelines are finalized, the list below may be modified accordingly.

Size of Label on Front Panel in Square Inches	Signal Word As Required Minimum Type Size All Capitals	"Keep out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	8 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix VI-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix VI-1. [40 CFR §162.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned toxicity category I on the basis of oral, inhalation or dermal toxicity the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix VI-1. (40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity categories I, II, and III. See Appendix VI-1. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or back) Panel for Additional Precautionary Statement" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix VI-1. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix VI-1. [40 CFR §162.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix VI-1. [40 CFR §162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. See Appendix VI-1. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix VI-3. The requirement is based on the results of the flash point determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flash point greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8 (c)(13)(ii) of Subpart D.

c. A "non-flammable aerosol" is one which meets the following criteria:

   i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii).

   ii. There is no flash back; and

   iii. The flash point of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the item "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazard of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. PRODUCT CLASSIFICATION: CLASSIFICATION LABELING REQUIREMENTS AND COMPLIANCE SCHEDULE - Section 3(d) of FIFRA requires that all pesticide formulations/uses be classified for either general or restricted use, and that those uses classified as restricted be limited to use by certified applicators or persons under their direct supervision (or subject to such other restrictions as may be imposed by regulation).

As indicated in Chapter II of this document, the Agency has: (1) indicated certain formulations/uses to be restricted based either on a previous classification determination made through the optional procedures of 40 CFR §162.30 or based on data already available to the Agency, or (2) indicated certain formulations/uses to be unrestricted based on data already available to the Agency, or (3) reserved any classification decision until appropriate short-term data are submitted. Uses have not been classified for general use at this time because such a decision requires an evaluation of chronic data most of which has yet to be generated.

The required product-specific data should be used by each registrant to make a classification determination following the criteria of 40 CFR §162.11(c) (Appendix VI-4). The draft label(s) submitted to the Agency as part of your application should reflect this determination and must be consistent with the terms of 40 CFR §162.10 and this guidance document with respect to label language and format for restricted use products. (No label changes with respect to classification are required for products with unrestricted uses.) The rationale supporting a classification proposal by the registrant that differs from a classification determination found in the document should be submitted with your application.

During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of §162.11(c). You will be notified of the Agency's classification evaluation.

A. Classification Labeling Requirements

1. Unrestricted Uses - No label changes with respect to a classification statement are necessary for those formulations/uses that are unrestricted.

2. Restricted Uses - Pesticide products bearing directions for use for formulations/uses classified restricted shall bear statements of restricted use classification on the front panel as described below:

   a. Front panel statement of restricted use classification.

      i. At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in 40 CFR §162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement, "Restricted Use Pesticide" shall appear.

ii. Directly below this statement on the front panel, a summary statement of the terms of restriction shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the administrator will define the appropriate wording for the terms of restriction by regulation.

3. Some But Not All Uses Restricted - If you determine that some uses should be classified RESTRICTED and some uses should be unrestricted, several courses of action detailed below are available:

i. You may delete all RESTRICTED uses and submit a draft label of the registration of your product to reflect only those uses that are unrestricted.

ii. Unrestricted uses may appear on a RESTRICTED label, but not vice versa. Therefore, you have the option of using a RESTRICTED USE label bearing all of your directions for use. If you choose this option, you may not distinguish those uses that are not unrestricted from those that are RESTRICTED.

iii. You may register two separate products with identical formulations, one containing only unrestricted uses and the other RESTRICTED uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the product names will be assigned separate registration numbers.

B. Compliance Schedules

1. Unclassified uses - None.

2. Restricted uses - The compliance schedule for restricted use products begins only after the approved label is returned to you as follows:

   a. No product with a use classified for restricted use under this first phase of reregistration may be released for shipment by the registrant or producer after the 120th day after the date of acceptance of the label submitted in conjunction with your application, unless such product bears the new accepted label or has supplemental labeling affixed or is accompanied by supplemental labeling. For the purposes of the first phase of reregistration, supplemental labeling means:

      i. an adhesive sticker containing the restricted use statement specified in 40 CFR 162.10(j)(2) and also found in this section;

      ii. a separate form containing the product name as it appears on the restricted use statement specified in 40 CFR §162.10(j)(2) and also found in this section; and

iii. the approved new label.

b. No product with a use classified for restricted use under this first phase of reregistration may be distributed or sold by retailers or other persons after the 270th day after the acceptance of the label submitted in conjunction with your application, unless such product bears the new accepted label or has supplemental labeling affixed or is accompanied by supplemental labeling.

c. No product with a use classified for restricted use under this first phase of reregistration may be released for shipment by the registrant or producer after the 270th day after the acceptance of the label submitted in conjuction with your application, unless such product bears the new accepted label.

d. In cases where a registrant chooses to delete product uses classified as restricted under the first phase of reregistration, no such product may be released for shipment by the registrant or producer after the 180th day after acceptance of the label submitted in conjuction with your application, unless such product bears the new accepted label.

e. No product with a use classified as restricted under this first phase of reregistration may be advertised without including the restricted use classification after the 120th day after the acceptance of the label submitted in conjuction with your application.

Brochures, technical pamphlets and similar material which are in final printed form on the date of acceptance of the new label may be distributed only for 270 days from the date of acceptance.

Item 9C. MISUSE STATEMENT - The following statement is required on your label: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Appendix VI-1. [40 CFR §162.10(1)(2)(ii)]

Item 10A. RE-ENTRY STATEMENT - If there is a reentry statement for your product, that statement will be set forth in the second chapter of the Document.

Item 10C. STORAGE & DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appenidx VI-5 of the latest specific storage and disposal product labels.

Item 10D. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix VI-5. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

C. Special (Child Resistant) Labeling Requirements

As required in 40 CFR 162.16 (Appendix VI-6), any pesticide that is released for shipment by the registrant after March 9, 1981, must be in special packaging if:

(1) its labeling permits residential use;

(2) it has not been classified for restricted use; and

(3) it meets the toxicity criteria of 40 CFR §162.16(c)(2).

Additional information on child resistant packaging is being developed and will be mailed to you shortly.

VI. Instruction for Submission

All applications prepared in response to this Notice should be addressed as follows:

Jay S. Ellenberger
Product Manager-12
Phone No. (703)
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, DC 20460

For each affected product for which continued registration is desired:

A. Within 90 days from receipt of this package you must submit the "FIFRA" Section (3)(c)(2)(B) Summary Sheet (Appendix IV-2) with appropriate attachments.

B. Within 6 months from receipt of this package you must submit:

1. "Application for Amended Pesticide Registration" (EPA Form 8570-11).

2. "Confidential Statement of Formula" (EPA Form 8570-4).

3. "Data Compensation Statement: Reregistration" (Appendix III-1).

4. Product Specific Data Report (Appendix III-2).

5. Two copies of any required product-specific data.

6. Two copies of draft labeling, including the label and associated brochures. If the current labeling conforms to the requirements of this Guidance Document and the results of the short term data, the registrant can submit such labeling. Otherwise, the labeling should be in draft form. The draft labeling should be either type-written text on 8-1/2 x 11 inch paper or a mock-up of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front and side panels, and the intended type sizes of the text.

7. A progress report on the development of generic mid-term and long-term data.

C. Within 24 months from the receipt of this package you must submit:

1. All required generic mid-term data (Table A).

2. A progress report on the development of generic long-term data (Table A).

DATA COMPENSATION STATEMENT: REREGISTRATION

EPA Reg. No.:______________________________

Product Name:______________________________

Applicant's Name & Address: ______________________________
____
____

Date of application for reregistration: ____________________

Registration Standard for products containing:____________________

Date Reregistration Standard Issued:____________________

Date Reregistration Guidance Document Issued:____________________

In connection with applicant's application for reregistration under the Registration Standard and Guidance Document identified above:

(A) Applicant offers to pay compensation to other persons to the extent required by sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

(B) Applicant understands and acknowledges that if EPA approves the application, the approval will be based solely on EPA's consideration of:

(1) All the generic data which, according to the Registration Standard and Guidance Document identified above, were found relevant to EPA's evaluation of the registrability of applicant's product (taking into account the product's composition and formulation category and the uses its label will permit); and

(2) The product-specific data listed on the form entitled "Product-Specific Data Report" which is part of this application.

(3) Applicant states that offers to pay compensation have been furnished to the persons and in the form specified by the Guidance Document identified above.

Dated:______________________________

Name of registrant's
authorized representative: ______________________________
(signature)

____
(typed)

Registration No.________

Reg. Std for ________
Date Reg. Std. Issued: ________
Guidance Package Date: ________

stration eline No.	Name of Test	Test not required for my Product Listed Above (Check Below)	I am complying with Data Requirements by		(For Use On Access Number Assign
			Citing MRID #	Submitting Data (attached) (check box)	
61-3	Product identity and disclosure ingredients				
-4	Description of manufacturing process				
-5	Discussion on formation of unintentional ingredient				
-6	Declaration and certification of ingredient limits				
-7	Product analytical methods and data				
61-8(1)	Color				
-8(2)	Odor				
-8(3)	Melting Point				
-8(4)	Solubility				
-8(5)	Stability				
	Octanol/water partition coefficient				
-8(7)	Physical State				
-8(8)	Density or specific gravity				
-8(9)	Boiling Point				
10)	Vapor pressure				
-8(11)	pH				
-8(12)	Storage stability				
-8(13)	Flammability				
-8(14)	Oxidizing or reducing action				
-8(15)	Explosiveness				
-8(16)	Miscibility				
	Viscosity				
[illegible]	Corrosion characteristics				
-8(19)	Dielectric breakdown voltage				
1-5(1)	Cage or pen field test				
-5(2)	Full-scale field test				
2-1	Fish acute LC_{50} - rainbow trout and bluegill				
-2	Acute toxicity to aquatic invertebrates				
-3	Acute toxicity to estuarine and marine organisms				
6(a)(1)	Short term simulated field test				
6(a)(2)	Long term simulated field test				
	Acute oral toxicity				
-2	Acute dermal toxicity				
-3	Acute inhalation toxicity				
	Primary eye irritation	64			

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier", or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standardq @nstitute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission.

   (2) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th 123456-Z; and the 27th, 123456-AA.

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000011318	Mattson, A.M.; Kahrs, R.A. (1969)
000011319	Mattson, A.M.; Kahrs, R.A. (1969)
000011320	Kahrs, R.A.; Kanuk, M.J. (1969)
000011321	Mattson, A.M.; Kahrs, R.A. (1969)
000011323	Mattson, A.M.; Kahrs, R.A. (1969)
000011324	Kahrs, R.A.; Kanuk, M.J. (1969)
000011325	Mattson, A.M.; Kahrs, R.A. (1969)
000011326	Kahrs, R.A.; Kanuk, M.J. (1969)
000011327	Getzin, L.W. (1967)
000011334	Kanuk, M.J.; Kahrs, R.A. (1969)
000011337	Kahrs, R.A.; Kanuk, M.J. (1969)
000011340	Polan, C.E. (1968)
000011341	Polan, C.E. (1967)
000011347	Ciba-Geigy Corporation (1977)
000011348	Heinrichs, L. (1976)
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000011403	Dupre, G.D. (1974)
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000011764	Tweedy, B.G. (1977)
000011786	Houseworth, L.D. (1977)
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000011827	Richardson, C. (1971)
000011828	Morton, H.V. (1971)
000011833	Guth, J.A. (1971)
000011839	Johnston, C.D. (1967)
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000011944	Beavers, J.B. (1979)
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000036942	Mattson, A.M. (1975)
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000060899	Mattson, A.M.; Kahrs, R.A. (1971)
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GS0034001	Ciba-Geigy, Ltd., Toxicology/Pathology (1973)
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GS0034003	Ciba-Geigy, Ltd., Basel, Switzerland, Toxicology/Pathology (1975)
GS0034004	Ciba-Geigy, Ltd., Toxicology/Pathology (1973)
GS0034005	Arni, P. (1980)
GS0034006	Arni, P. (1980)
GS0034008	Hool, G. (1980)
GS0034009	Ciba-Geigy, Ltd., Toxicology/Pathology (1976)
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005011895	Townsend, L.R.; Specht, H.B. (1975)
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005020908	Guerzoni, M.E.; Del Cupolo, L.; Ponti, I. (1976)
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GENERIC DATA EXEMPTION STATEMENT

Product Registration Number: ______________________________

egistrant's Name: ______________________________

s an authorized representative of the registrant of the roduct identified above, I hereby certify that:

1) I have read and am familiar with the terms of a Notice in a Guidance Document from EPA dated ____________ concerning a requirement for submission of generic data on the active ingredient ______________________________ under FIFRA Section 3(c)(2)(B).

2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the data in question, on the grounds that the product is an end-use product and it contains the active ingredient solely as the result of the incorporation into the product (during formulation or packaging) of a manufacturing-use product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

3) An accurate confidential formula statement for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient in my firm's product. My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertaking made in this statement, my firm's product's registration may be suspended in accordance with FIFRA Section 3(c)(2)(B).

ated: ______________________

egistrant's authorized
representative:

____
(Signature)

____
(Typed)

FIFRA §3(C)(2)(B) SUMMARY SHEET

EPA Registration No.:__________________________________
Product Name:__________________________________
Applicant's Name:__________________________________
Registration Standard for Products Containing:________________
Data Registration Standard Issued:________________________
Data Guidance Document Issued:__________________________

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(c)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

1. ☐ Attached is a completed "Generic Data Exemption Statement."

2. ☐ I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

3. ☐ I have entered into an agreement with one or more other registrants under FIFRA § 3(c)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by (name of other registrant).

4. ☐ I enclose a completed "Statement of willingness to Enter Into an agreement with Other Registrants for Development of Data" with respect to the following data requirements:

5. ☐ I request that you amend my registration by deleting the following uses:

6. ☐ I request voluntary cancellation of the registration of this product.

Dated:__________________

Registrant's authorized
representative:

____
(signature)

____
(typed)

STATEMENT OF WILLINGNESS TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(1) I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document dated ____________ to submit data concerning the active ingredient ________________________________:

Name of Firm	EPA Company Number

(This firm or group of firms is referred to below as "my firm".)

(2) My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

(3) My firm has offered in writing to enter into such an agreement, and has offered to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Firm	Date of Offer

However, none of those firm(s) accepted my offer.

(4) My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit the data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B).

Dated:________________ ______________________________
(Signature)

____
(Typed)

Physical - Chemical Hazards

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flash points at or below 20°F; or if there is a flashback at any valve opening	Extremely Flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20° and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS.	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperature above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Above 150°F	None Required

6. Paper and plastic bags

Dispose of bags according to approved Federal, State or local procedures under the Resource Conservation and Recovery Act.

7. Compressed gas cylinders

Return empty cylinder for reuse (or similar wording).

PROPOSED DISPOSAL STATEMENTS FOR PESTICIDES

PESTICIDE DISPOSAL (all except household)

Pesticide, spray mixture or rinsate that cannot be used according to label instructions must be disposed of according to Federal, State or local procedures under the Resource Conservation and Recovery Act.

CONTAINER DISPOSAL

1. Household (all)

Do not reuse empty container (bottle, can, bucket).
Wrap (container) and put in trash collection.

2. Metal (all sizes)

Triple rinse (or equivalent) and offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by other approved State and local procedures.

3. Plastic (all)

Triple rinse (or equivalent) and offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by incineration if permitted by State and local authorities.

4. Glass (all)

Triple rinse (or equivalent) and dispose of in a sanitary landfill or by other approved State and local procedures.

5. Fiber drums with liners

Dispose of liners according to approved Federal, State or local procedures under the Resource Conservation and Recovery Act. If container cannot be reused*, dispose of in a sanitary landfill or by incineration if permitted by State and local authorities.

*Manufacturer should replace this phrase with one indicating whether and how fiber container may be reused.

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached [illegible] such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170–189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as 'safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of

the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups: those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC_{50}	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter	From 2. thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LC_{50}	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.

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Hazard indicators	Toxicity categories			
	I	II	III	IV
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Required signal word, all capitals	"Keep out of reach of Children"
	Points	Points
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel statement of practical treatment required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

(A) PRESSURIZED CONTAINERS

Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.

(B) NONPRESSURIZED CONTAINERS

Flash point	*Required text*
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

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(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv)).

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for

use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

APPENDIX VI-2

TABLE D

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT OF LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product Name	All Products	Front panel	Center front panel	
2	Company Name and Address	All Products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for..." "Distributed by...," etc.
3	Net Contents	All Products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S units.
4	EPA Est. No.	All Products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All Products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients Statement	All Products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/Gallon Statement	Liquid products where dosage given as lbs ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front Panel Precautionary Statements	All Products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.

TABLE E

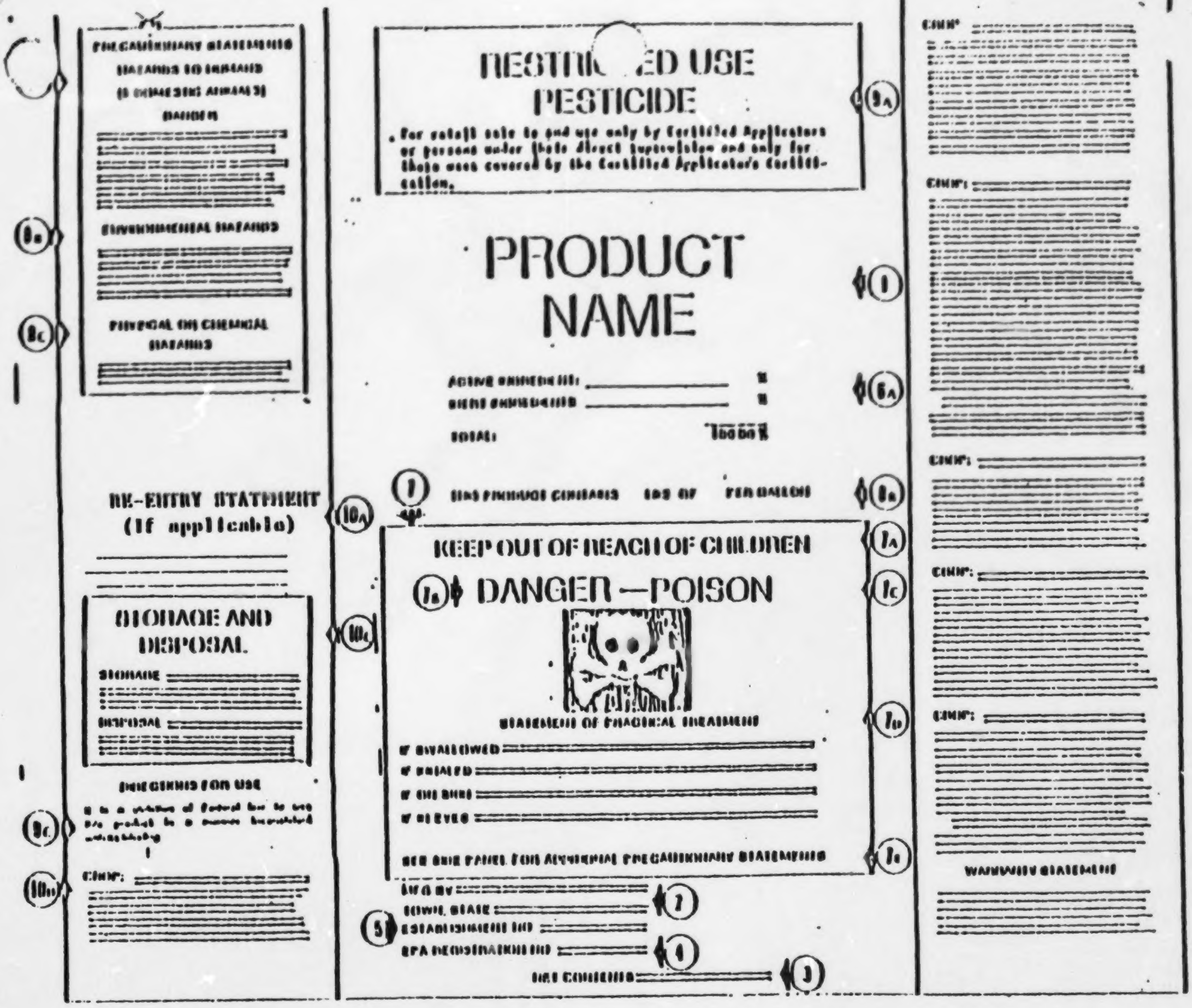
ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT OF LABEL		COMMENTS
			REQUIRED	PREFERRED	
7A	Keep Out of Reach of Children (Child Hazard Warning)	All Products	Front panel	Above signal word	Note type size requirements.
7B	Signal Word	All Products	Front panel	Immediately below Child Hazard Warning	Note type size requirements.
7C	Skull & Crossbones and word "POISON" (in red)	All products which are Category I based on oral, dermal or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements	Front panel for all	
7E	Referral Statement	All products where precautionary labeling appears on other than front panel	Front panel		

TABLE F-1

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT OF LABEL		COMMENTS
			REQUIRED	PREFERRED	
8	Side/Back Panel Precautionary Statements	All Products	None	Top or side of back panel preceding Directions for Use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to Humans and Domestic Animals	All Products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental Hazards	All Products	None	Same as above	Environmental hazards include bee caution where applicable.
8C	Physical or Chemical Hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted Block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse Statement	All products	Immediately following Statement of Classification or ahead of Directions for Use		
10A	Re-entry Statement	All Cholinesterase Inhibitors	In the Directions for Use	Immediately after Misuse Statement	

TABLE F-2

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT OF LABEL		COMMENTS
			REQUIRED	PREFERRED	
10C	Storage and Disposal Block	All products	In the Directions for Use	Immediately before specific directions for use or at the end of Directions for Use	Must be grouped together, and preferably blocked. Heading must be same type size as Child Hazard Warning.
10D U.S.	Directions for Use	All products	None	None	May be in metric units as well as U.S. units.



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

RE-ENTRY STATEMENT
(If applicable)

STORAGE AND DISPOSAL

STORAGE

DISPOSAL

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

CROP:

RESTRICTED USE PESTICIDE

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification.

PRODUCT NAME

ACTIVE INGREDIENT: ____ %
INERT INGREDIENTS ____ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

DANGER—POISON

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO
EPA REGISTRATION NO
NET CONTENTS

CROP:

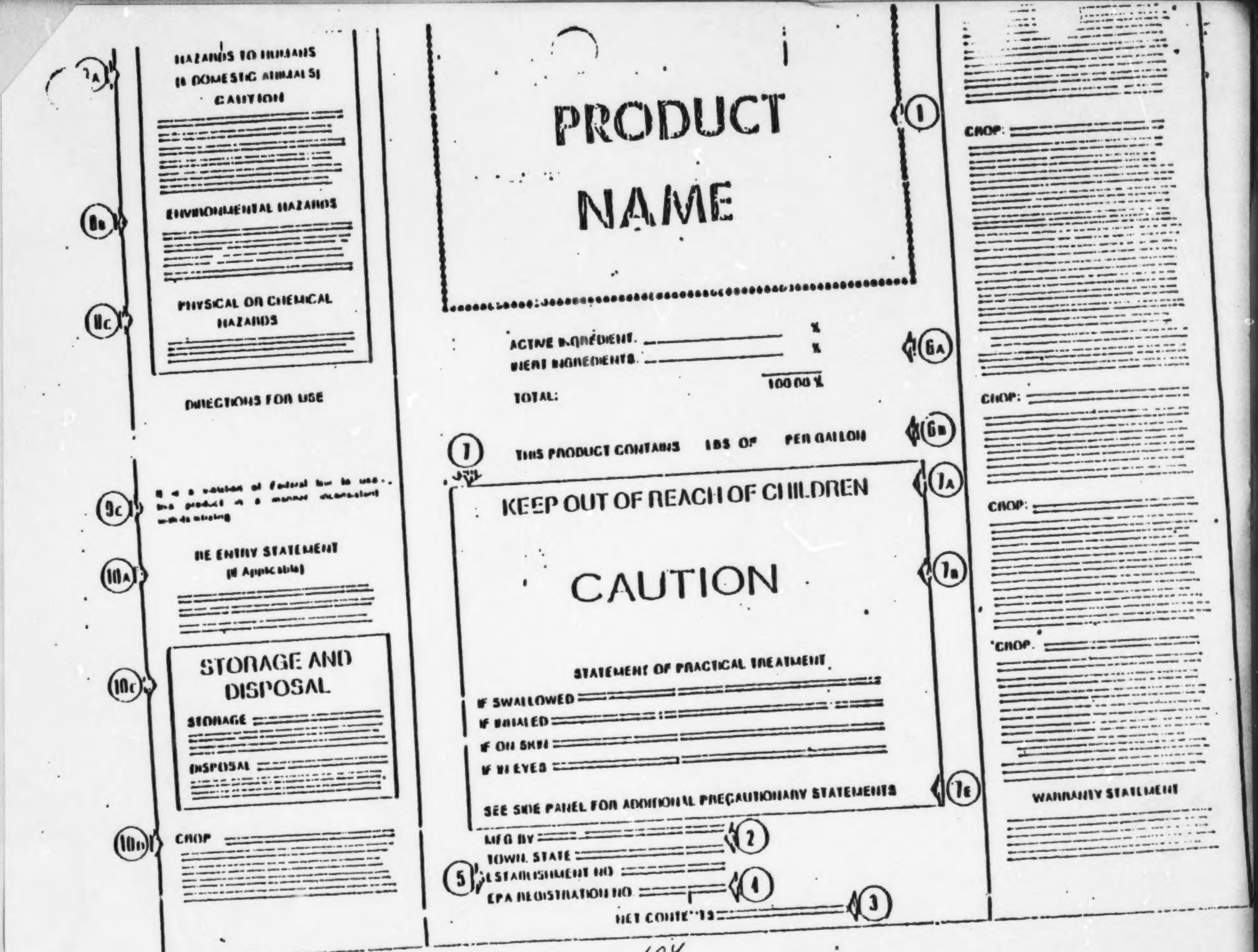
CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT



8A
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
CAUTION
8B
ENVIRONMENTAL HAZARDS
8C
PHYSICAL OR CHEMICAL
HAZARDS
DIRECTIONS FOR USE
9C
It is a violation of Federal law to use this product in a manner inconsistent with its labeling
10A
RE ENTRY STATEMENT
(If Applicable)
10C
STORAGE AND
DISPOSAL
STORAGE
DISPOSAL
10D
CROP
PRODUCT
NAME
1
ACTIVE INGREDIENT: %
INERT INGREDIENTS: %
TOTAL: 100.00 %
6A
THIS PRODUCT CONTAINS LBS OF PER GALLON
6B
7
7A
KEEP OUT OF REACH OF CHILDREN
7B
CAUTION
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
7E
MFG BY
TOWN, STATE
2
5
ESTABLISHMENT NO
EPA REGISTRATION NO
4
NET CONTENTS
3
CROP:
CROP:
CROP:
CROP:
WARRANTY STATEMENT